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Guidance for the Reregistration of Pesticide Products Containing Anilazine (080811) as the Active Ingredient

(U.S.) Environmental Protection Agency
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National Technical Information Service
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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING ANILAZINE (080811) AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, DC 204060

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15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement:	19. Security Class (This Report)	21. No. of Pages 89
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(See ANSI-Z39.18) See Instructions on Reverse OPTIONAL FORM 272 (4-77) (Formerly NTIS-35) Department of Commerce

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Also attached to this document are copies of the letters sent to registrants to transmit this document and notify them of studies required.

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic

suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time-frames outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION AND RATIONALE

A. Introduction

This Registration Standard describes the regulatory position of the Environmental Protection Agency (EPA or the Agency) on registration of manufacturing-use products (MP) containing the fungicide anilazine. The Agency's position is based on a consideration of available data and on an evaluation of all registered uses and registered MPs with anilazine as an active ingredient.

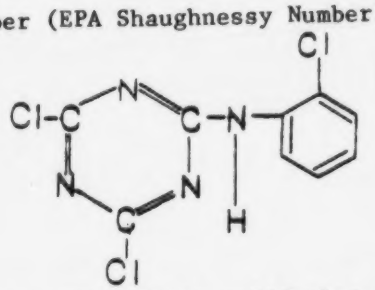
This position is based on a number of considerations. Foremost among these is an analysis of anilazine data based on the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations. The Standard also considers labeling requirements, tolerances, "Special Local Needs" registrations authorized by Section 24(c) of the FIFRA as well as Federal registrations granted under Section 3 of the FIFRA. Finally, the Agency sets forth the data requirements that must be met to register or reregister products covered by the Standard.

This Standard only addresses registration requirements for current or substantially similar future MPs and their intermediaries. Anilazine MPs that differ appreciably from those described here may require amendments to the Standard. Additionally, use patterns which differ from those described here may also require amendments to the Standard.

B. Description of Chemical

Anilazine is the acceptable common name for 2,4-dichloro-6-(O-chloroanilino)-s-triazine recognized by the British Standards Institution and the International Standardization Organization. Trade names and other

names for anilazine are: Dyrene, Direz, Kemate, Triasyn, B-622, Ent-26,058, HCl-C08684, and 4,6-dichloro-N-(2-chlorophenyl)-1,3,5-triazin-2-amine. The Chemical Abstracts Service (CAS) Registry Number is 101-05-3. The OPP Internal Control Number (EPA Shaughnessy Number) is 080811. The structural formula is:



Anilazine is a white to tan crystalline solid that is practically non-volatile. The empirical formula is $C_9H_5Cl_3N_4$. The melting point of anilazine is 159-160°C. It is insoluble in water, but is soluble in chlorobenzene, toluene, xylene and acetone.

Anilazine was developed by Ethyl Corporation and Pittsburgh Coke and Chemical Company. It is manufactured by Mobay Chemical Corporation under license from Ethyl Corporation, owner of the patent rights.

C. Use Profile

Anilazine is a protectant foliar fungicide registered to control a number of fungal plant pathogens on turf, tobacco, ornamentals and various fruits and vegetables. Approximately 80% of the anilazine produced is used on turf, tomatoes and celery. The compound is also registered as a fungicidal additive to vinyl plastics.

At present there are 33 formulated products, 2 technical products and 2 formulating intermediates federally registered containing anilazine as a single active ingredient. Three additional multiple active ingredient products containing anilazine are registered. In addition to the federal registrations, 5 intrastate products and 2 "Special Local Needs" are

registered.

D. Regulatory Position

Based on a scientific and technical evaluation of the available data and other relevant information on the chemical, the Agency has made the following determinations regarding anilazine:

1. Manufacturing-use pesticide products containing anilazine as a sole active ingredient or mixed with other active ingredients may be registered for sale, distribution and use subject to the terms and conditions specified in this Standard.

2. Because of the extensive data gaps for anilazine, the Agency is not able to evaluate all of the hazards that are routinely evaluated. However, based on the available data, anilazine has not been demonstrated to cause unreasonable adverse effects in man when used in accordance with prescribed label directions and precautions.

3. A review of available studies has identified potential environmental concerns. Results of these studies indicate a very high acute toxicity to fish and aquatic invertebrates.

Anilazine is federally registered for use on cranberries in Wisconsin only. This cranberry acreage is in close proximity to aquatic environments. The potential exists for aquatic species to be adversely affected via release of water containing anilazine into the aquatic environment, drift or inadvertant direct application. Due to a lack of environmental fate data, it is not possible to estimate the hazard to non-target organisms. Once the Agency has evaluated these additional data, it will determine if continued registration of products containing

anilazine for use on cranberries is warranted or whether additional restrictions are needed.

4. Registrants must agree to develop or provide additional data, as specified in Tables A and B located in Chapter IV of this document, in order to maintain existing registrations or to permit new anilazine registrations.

5. Tolerance reassessment is normally a part of the Registration Standard review process. Due to the absence of pertinent data, the Agency is unable to complete its reassessment of anilazine tolerances. Specifically, the Agency is unable to establish a valid "No Observed Effect Level" (NOEL) or determine an "Acceptable Daily Intake" (ADI) for anilazine. The Agency will complete its tolerance assessment when the data gaps have been satisfied.

Summary of present tolerances for anilazine (in parts per million):

	Canada	Mexico	Codex	U.S.
Blackberries	5.0	-	-	10.0
Blueberries	10.0	-	-	10.0
Celery	10.0	-	-	10.0
Cranberries	10.0	-	-	10.0
Cucumbers, inc pickles	5.0	-	-	10.0
Dewberries	10.0	-	-	10.0
Garlic	10.0	-	-	1.0
Onions, dry bulb	10.0	-	-	1.0
Onions, green	10.0	-	-	10.0
Potatoes	1.0	-	-	1.0

Loganberries	5.0	-	-	10.0
Melons	5.0	-	-	10.0
Pumpkin, inc squash	5.0	-	-	10.0
Raspberries	5.0	-	-	10.0
Shallots	10.0	-	-	10.0
Summer squash	5.0	-	-	10.0
Strawberries	20.0	-	-	10.0
Tomatoes	10.0	-	-	10.0
Winter squash	5.0	-	-	10.0

E. Regulatory Rationale

The Agency has determined that it can allow the registration of anilazine after considering the following:

1. Anilazine is degraded rapidly in both moist and dry soils under aerobic conditions, with half-lives of 0.5 and 2.5 days, respectively. Anilazine is moderately mobile in sandy loam soil, but slightly mobile in agricultural sand, sandy clay loam, silt loam, and silty clay soils.

2. There is sufficient information to characterize anilazine as practically non-toxic to birds and honey bees. This chemical has been found to be highly toxic to fish and aquatic invertebrates. Strict adherence to application techniques as prescribed in the label directions and precautions will minimize the risk of potential adverse effects to aquatic organisms.

3. Acute oral studies reviewed show anilazine to be a low risk chemical. The studies submitted placed anilazine in Category II (rabbit), III (rat) and IV (dog). An acute dermal study on the rabbit placed the chemical in

Category III for dermal effects. However, the Agency considers anilazine to be a skin sensitizer. Strict adherence to application techniques and precautionary statements as outlined on the label will minimize exposure.

4. There are currently no data available to establish safe reentry intervals for anilazine-treated areas, thus no reentry intervals have been established. Since dermal exposure to anilazine has been shown to result in skin irritations, reentry data are needed to establish safe reentry intervals. Until such data have been developed and evaluated, an interim 24 hour reentry interval is required.

5. It is not the Agency's policy to cancel or to withhold registration merely because data are missing or inadequate [see FIFRA Sections 3(c)(2)(B) and 3(c)(7)]. Rather, publication of this Standard provides a mechanism for identifying data needs, and registration of anilazine under this Standard allows for the upgrading of labels during the period in which the required data are being developed. These data will be reviewed and evaluated when they are received and the Agency will determine, at that time, whether they will affect the registrations of anilazine.

F. Criteria for Registration Under This Standard

To be covered by this Standard, products must contain anilazine as the sole active ingredient or in combination with other active ingredients, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section G of this document.

The applicant for registration or reregistration of products subject

to this Standard must comply with all terms and conditions described in it. That includes making a commitment to fill data gaps on a schedule agreed to by both this Agency and the applicant. Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

G. Acceptable Ranges and Limits

1. Product Composition

To be covered under this Standard, technical grade products must contain at least 92 percent anilazine as the sole active ingredient. Each MP formulation proposed for registration must be fully described with appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade products and MP's containing anilazine for any acute toxicity category, provided the labeling of those products bear appropriate precautionary statements.

3. Use Patterns

To be registered under this Standard, MP's containing anilazine may be labeled for formulation only into end-use products for:

° Terrestrial, food crops on: tomatoes, celery, blackberries, dewberries, loganberries, raspberries, strawberries, blueberries, huckleberries, cucumbers, onions (green and bulb or dry), garlic

shallots, potatoes, pumpkins, squash, melons and cranberries (Wisconsin only).

- Terrestrial, non-food crops on: tobacco
- Domestic, outdoor on: gladioli, lawns and turf (bluegrasses, bent grasses, rye grasses and fescues).

H. Required Labeling

All technical grade and MP products containing anilazine must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements.

1. Manufacturing-Use

In addition to the labeling as described above, the labels of all MP's must contain the following statements:

- "For formulation into end-use fungicide products intended for domestic and non-domestic outdoor terrestrial use on (crops to be specified)."
- "This pesticide is toxic to fish and aquatic invertebrates. Do not discharge into lakes, streams, ponds or public water unless in accordance with an NPDES permit. For guidance, contact your Regional Office of EPA."
- "Protective clothing should be worn during periods of exposure, such as, during application or when contacting treated foliage."

2. End-Use Products

The following labeling recommendations are being made at this time

based on current use patterns and based on review of available data. Additional labeling statements may be needed upon receipt and evaluation of the data requested in this Standard.

All sites (except cranberries)-

- "This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water or wetlands. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover or incorporate spills."

Cranberries only-

- "This pesticide is toxic to fish and aquatic invertebrates. Movement from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover and incorporate all spills."

All sites -

- "Do not use on seed crops intended to be used for feed or forage. Do not graze treated areas."
- "Do not reenter treated fields within 24 hours following application of this product."
- "Protective clothing should be worn during periods of exposure, such as during application or when contacting treated foliage."

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/ Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted 2/. Any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 3/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Produc-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ USEPA, 1982. Pesticide Registration; Proposed Data Requirements - Part 158. FEDERAL REGISTER of November 24, 1982 (47 FR 53192)

3/ USEPA, 1983. Pesticide Assessment Guidelines, National Technical Information Service, Springfield, VA.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)
to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Yes	GS01140021,GS01140023	No
61-2 - Statement of Composition	TGAI	No		Yes
61-3 - Discussion of Formation of Ingredients	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	No		Yes
62-2 - Certification of Limits	TGAI	No		Yes
62-3 - Analytical Methods for Enforcement of Limits	TGAI	Partially	GS01140022	Yes 3/
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	GS01140024 6/,GS01140025 6/	Yes 4/
63-3 - Physical State	TGAI	Yes	GS01140024 6/,GS01140025 6/	No
63-4 - Odor	TGAI	No		Yes
63-5 - Melting Point	TGAI	Yes	GS01140024 6/,GS01140025 6/	Yes 4/
63-6 - Boiling Point	TGAI	Not Applicable		
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	GS01140024 6/,GS01140025 6/	Yes 4/

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2]
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI OR PAI	Partially	GS01140024[6], GS01140025[6]	Yes [5]
63- 9 - Vapor Pressure	PAI	No		Yes
63-10 - Dissociation constant	PAI	No		Yes
63-11 - Octanol/water partition coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	Yes	GS01140024[6], GS01140025[6]	Yes [4]
Other Requirements:				
64- 1 - Submittal of samples	Choice	Not Applicable		

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

§158.120 Product Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than 6 months from the date of this Standard.
3/ Quantitative methods are required to determine impurities present at >0.1% by weight.
4/ This information must be submitted for the 92% technical formulation.
5/ The lack of a specific quantity for water solubility constitutes a data gap as does the presentation of solubilities in other solvents at 30°C (rather than the required 20°C). (Solubility should be expresses in terms of g/100 ml of solvent at 20°C (68°F) or in terms of ppm (mg/kg)).
6/ Submitted by Mobay Chemical Company. May be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirements	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	No		Yes
- Livestock	PAIRA and plant metabolites	No		Yes
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Yes	GS01140004 [24]	Yes [3]
- Animal residues	TGAI and metabolites	No		Yes [4]
171-4 - Storage Stability Data	PAI	No		Yes
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
- Crop Group #1 - Root and Tuber Vegetables				
o Crop 1 - Potatoes				
-- Crop field trials	TEP	Partial	GS01140005 [24], GS01140006 [24]	Yes [5]
-- Processed Food/Feed	EP	No		Yes [6]

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue- Residue Studies for Each Food Use				
- Crop Group #2 - Bulb Vegetables (Allium spp.)				
° Crop 1 - Garlic				
-- Crop Field Trials	TEP	Partially	GS01140007 24/	Yes 7/
-- Processed Food/Feed	EP	Not Applicable		
° Crop 2 - Onions (green & dry bulb)				
-- Crop Field Trials	TEP	Partially	GS01140007 24/, GS01140008 24/	Yes 8/
-- Processed Food/Feed	EP	Not Applicable		
° Crop 3 - Shallots				
-- Crop Field Trials	TEP	Partially	GS01140009 24/	Yes 9/
-- Processed Food/Feed	EP	Not Applicable		
- Crop Group #3 - Leafy Vegetables				
° Crop 1 - Celery				
-- Crop Field Trials	TEP	Partially	GS01140010 24/, GS01140011 24/	Yes 10/
-- Processed Food/Feed	EP	Not Applicable		

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue- Residue Studies for Each Food Use				
- Crop Group #4 - Fruiting Vegetables (except cucurbits)				
° Crop 1 - Tomatoes				
-- Crop Field Trials	TEP	Partially	GS01140005 [24]	Yes [11]
-- Processed Food/Feed	EP	No		Yes [12]
- Crop Group #5 - Cucurbit Vegetables				
° Crop 1 - Cucumbers				
-- Crop Field Trials	TEP	Yes	GS01140012 [24]	No [13]
-- Processed Food/Feed	EP	Not Applicable		
° Crop 2 - Melons				
-- Crop Field Trials	TEP	Partially	GS01140013 [24]	Yes [14]
-- Processed Food/Feed	EP	Not Applicable		

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue- Residue Studies (continued)				
° Crop 3 - Pumpkins				
-- Crop Field Trials	TEP	Partially	GS01140014 24/	Yes 15/
-- Processed Food/Feed	EP	Not Applicable		
° Crop 4 - Squash (summer)				
-- Crop Field Trials	TEP	Yes	GS01140015 24/	No 16/
-- Processed Food/Feed	EP	Not Applicable		
° Crop 5 - Squash (winter)				
-- Crop Field Trials	TEP	Partial	GS01140015 24/	Yes 17/
-- Processed Food/Feed	EP	Not Applicable		
- Crop Group #6 - Small Fruits and Berries				
° Crop 1 - Blackberries				
-- Crop Field Trials	TEP	Partial	GS01140016, GS01140017 24/ 24/	Yes 18/
-- Processed Food/Feed	EP	Not Applicable		

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue Residue Studies (continued)				
- Crop Group #6 - Small Fruits and Berries				
° Crop 2 - Blueberries (huckleberries)				
-- Crop Field Trials	TEP	Partial	GS01140018 24/	Yes 19/
-- Processed Food/Feed	EP	Not Applicable		
° Crop 3 - Cranberries				
-- Crop Field Trials	TEP	Partial	GS01140019 24/	Yes 20/
-- Processed Food/Feed	EP	Not Applicable		
° Crop 4 - Dewberries and Loganberries				
-- Crop Field Trials	TEP	Partial	GS01140017 24/	No 21/
-- Processed Food/Feed	EP	Not Applicable		
° Crop 5 - Raspberries				
-- Crop Field Trials	TEP	Partial	GS01140017 24/	No 21/
--Processed Food/Feed	EP	Not Applicable		

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- Crop Group #6 - Small Fruits and Berries				
° Crop 6 - Strawberries				
-- Crop Field Trials	TEP	Partial	GS01140020 24/	Yes 22/
-- Processed Food/Feed	EP	Not Applicable		
- Crop Group #7 - Miscellaneous Commodities				
° Crop 1 - Tobacco				
-- Crop field trials	TEP	No		Yes 23/
-- Processed Food/Feed	EP	Not Applicable		
- Potable Water	EP	Not Applicable		
- Fish	EP	Not Applicable		
- Irrigated Crops	EP	Not Applicable		
-- Field trials	EP	Not Applicable		
-- Processed Food/Feed	EP	Not Applicable		
- Food Handling	EP	Not Applicable		
- Meat/milk/poultry/eggs	TGAI or plant metabolites	No		Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

§158.125 Residue Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.
2/ Data must be submitted no later than 6 months from the date of this Standard.
3/ Tolerances for anilazine residues in or on plants are currently expressed in terms of the parent compound only. Should plant metabolism studies show the parent compound is the only residue of concern, then the analytical method submitted is adequate for analysis, but not for tolerance enforcement because other compounds (parathion, methyl parathion, guthion, amitrole, chlorpropham, dinoseb and diuron) may interfere. In this case, the following data gaps exist:
° Suitable methods are required for enforcement of all tolerances expressed in terms of the parent compound. If the residues of concern in plants are determined to be compounds other than the parent moiety, then a suitable method would be required which determines these residues.
° A confirmatory test for anilazine residues in plants is required.
4/ Required unless feeding studies indicate the feed uses are to be classified in category 3 of 40 CFR 180.6 (a), i.e., no tolerances are required.
5/ The following additional data are required:
° Field trials conducted in CA and either in ID, OK or WA which include multiple foliar applications (no less than 12 at weekly intervals) with the 50% WP at 2.5 lb ai/A using ground and aerial equipment.
° Field trials conducted in northeastern and northwestern growing regions which include multiple foliar applications (no less than 12 weekly intervals) with the 5%D at 2.0 lb ai/A using ground and aerial equipment. The data should reflect residues from multiple applications (12 - 16) at the highest permissible application rate applied up to the time of harvest.
6/ A processing study for dried potatoes, potato granules and chips will be required.
7/ The following additional data are required:
° Field trials in CA reflecting multiple foliar applications (no less than 16 at weekly intervals) with the 5%D and 50% WP at the maximum recommended rate of 2 and 3 lbs ai/A, respectively, using ground and aerial application and subsequent residue analysis of the dry bulbets (cloves) applied up to the time of harvest.
8/ The following additional data are required:
° Field trials on green onions reflecting multiple foliar applications (green onions from sets require no less than four treatments at weekly intervals; green onions from seed require no less than 16 treatments at weekly intervals) with the 5%D and 50% WP at the maximum recommended rates of 2 and 1.5 lb ai/A, respectively, using ground and aerial equipment and subsequent residue analysis of the whole plant. Adequate geographic representation must be used (TX, CA or AZ).

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

§158.125 Residue Chemistry
(continued)

° Field trials on bulb onions reflecting multiple foliar applications (no less than 16 at weekly intervals) with the 5% D and 50% WP at the maximum recommended rates of 2 and 3 lbs ai/A, respectively, using ground and aerial equipment and subsequent residue analysis of the dry bulbs up to the time of harvest. Adequate geographic representation must be used (OK or WA, CA and MI).

9/ The following additional data are required:
° Field trials reflecting multiple foliar applications (no less than 16 at weekly intervals) with the 5% D at 2 lb ai/A using ground and aerial equipment and subsequent residue analysis of the whole plant. Tests must be conducted in LA.

10/The following additional data are required:
° Twelve weekly applications of the 5% D at 2 lb ai/A in CA or OR using aerial and ground equipment.
° Tests conducted in western locations (CA or OR) using the 50% WP at 3 lbs ai/A using both ground and aerial applications (12 weekly treatments per season).

11/The following additional data are required:
° Residue data from western locations, particularly CA using both the 50% WP and 5% D formulations at 2.5 lbs ai/A and 1.5 lbs ai/A, respectively, and using both ground and aerial equipment. At least eight weekly applications must be made.

12/Residue data for the processed products of tomatoes (catsup, juice, puree and wet and dry pomace) must be submitted to determine the necessity of food/feed additive tolerances.

13/Consideration should be given to a lower tolerance based upon the fact that the highest anilazine residue level encountered was 1.23 ppm. A 5 ppm tolerance would be more appropriate.

14/The following additional data are required:
° Tests (8 applications) conducted in western locations, particularly CA, using both the 5% D and 50% WP at 3 lbs ai/A and using both ground and aerial equipment.

15/The following additional data are required:
° Residue data from tests conducted in western, eastern and southern locations using both the 50% WP and 5% D formulations at 3 lbs ai/A. Twelve treatments must be applied using aerial and ground equipment.

16/Consideration should be given to a lower tolerance. A tolerance of 5 ppm would be more appropriate.

17/The following additional data are required:
° Tests conducted in southern and western locations using both the 5% D and 50% WP at 3 lbs ai/A and using ground and aerial equipment.

18/The following additional data are required:
° Residue data for blackberries following 10 or more aerial and ground applications of the 5% D and 50% WP at 3 and 2 lbs ai/A, respectively, made at weekly intervals in OR or WA.

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

§158.125 Residue Chemistry
(continued)

19/ The following additional data are required:
° Residue data for blueberries reflecting at least 10 weekly aerial and ground applications of the 50% WP at 1.5 lb ai/A.

20/ The following additional data are required:
° Residue data reflecting 16 weekly aerial and ground applications of the 50% WP at 3 lbs ai/A conducted in WI.

21/ When the requested data for blackberries are provided, they will be translated to dewberries, loganberries and raspberries.

22/ The following additional data are required:
° Residue data reflecting 8 weekly aerial and ground applications of the 5% D and 50% WP at 2 and 3 lbs ai/A, respectively.

23/ The following data are required to assess the exposure of man to residues of anilazine in or on tobacco:
° Residue analysis of green tobacco after the last of at least 7 foliar treatments with the 50% WP at 1 lb ai/A using ground and aerial equipment.
° If residues in green tobacco are >0.1ppm, pyrolysis products must be characterized.

24/ Submitted by Mobay Chemical Corporation. May be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [3]
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,H	No		Yes [4]
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B	No		Yes
161-3 - On soil	TGAI or PAIRA	A,B	No		Yes
161-4 - In Air	TGAI or PAIRA	A,B	No		No [5]
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,H	No		Yes [6]
162-2 - Anaerobic Soil	TGAI or PAIRA	A,B	No		Yes
162-3 - Anaerobic Aquatic	TGAI or PAIRA	A	No		Yes [7]
162-4 - Aerobic Aquatic	TGAI or PAIRA	A	No		Yes
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,H	Partially [8]	00025729 [17]	Yes
163-2 - Volatility (Lab)	TEP	A,B	No		Yes
163-3 - Volatility (Field)	TEP	A,B	No		Yes [9]

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B,H	No		Yes
164-2 - Aquatic (Sediment)	TEP	A	No		Yes
164-3 - Forestry	TEP	-	No		No 10/
164-4 - Combination and Tank Mixes	-	-	No		No 11/
164-5 - Soil, Long-term	TEP	A,B	No		No 12/
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A,B	No		Yes
165-2 - Rotational Crops (Field)	TEP	A,B	No		Yes 13/
165-3 - Irrigated Crops	TEP	A	No		Yes
165-4 - In Fish	TGAI or PAIRA	A,B	No		Yes 14/
165-5 - In Aquatic Non-Target Organisms	TEP	A	No		Yes 15/
158.145 Reentry Studies	-	A,B	No		Yes 16/

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than 48 months.
4/ Hydrolysis studies: One study was reviewed (05001459) that is scientifically invalid because it was not carried out in darkness. All data are required.
5/ Photodegradation in Air: No data were submitted; however, no data are required because anilazine does not have a greenhouse use.
6/ Aerobic soil metabolism studies: One study was reviewed (05001459) that is scientifically valid but does not partially or totally fulfill data requirements because a 50% commercial formulation was used and not the technical or purer grade of anilazine. All data are required.
7/ Anaerobic aquatic metabolism studies: No data were submitted, but all data are required. The anaerobic aquatic metabolism data may be substituted for the anaerobic soil metabolism data, but the reverse is not permissible.
8/ Leaching and adsorption/desorption studies: Two studies were reviewed; one study (00065859) is scientifically invalid because anilazine could not be detected with enough precision by using a nonspecific fungal bioassay. The other study (00025729) is scientifically valid and partially fulfills data requirements by providing soil TLC mobility data on anilazine in six soils. To satisfy the terrestrial food crop uses, a study is needed to assess the mobility of anilazine and its degradates after the pesticide has been aged in soil. Soil TLC, soil column, or batch equilibrium (adsorption/desorption) techniques may be utilized. To satisfy the mobility data requirements for the domestic outdoor use, batch equilibrium (adsorption/desorption) studies on a minimum of four soils, such as sand (agricultural), sandy loam, silt loam, clay, or clay loam are required. For the aquatic use, batch equilibrium (adsorption/desorption) studies on one aquatic sediment obtained from or representative of the aquatic use area are required.
9/ Laboratory and field volatility studies: No data were submitted, but all data are required for the laboratory volatility studies. All data may be required for the field volatility studies based on the results of the laboratory studies.
10/ Forestry dissipation studies: No data were submitted; however, no data are required because anilazine does not have a forestry use.
11/ Dissipation studies for combination products and tank mixes uses: This data requirement is currently not being implemented for this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

§158.130 Environmental Fate
(continued)

12/ Long-term field dissipation studies: No data were submitted. Data requirements for long-term field dissipation studies will be predicated upon the results of the terrestrial field dissipation study.

13/ Field accumulation studies on rotational crops: No data were submitted. Data requirements for field accumulation studies on rotational crops will be based on the results of confined accumulation studies on rotational crops.

14/ Laboratory studies of pesticide accumulation in fish: No data were submitted; however, data may be required. Fish accumulation data will not normally be required in situations where the registrant can offer evidence acceptable to the Agency showing that the active ingredient and/or its principal degradation product(s):

(i) Will not reach water, or
(ii) Will not persist in water (i.e., has a half-life of about 4 days or less), or
(iii) Has a relatively low potential for accumulation in fish as indicated by an octanol/water partition coefficient less than about 1000.

15/ Required for use on cranberries only.

16/ Registrant is required to submit reentry data and recommendations for safe reentry intervals. An interim 24 hour reentry interval is tentatively required.

17/ Submitted by Mobay Chemical Company. May be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A,B,H,I	Yes	00070075	No
81-2 - Dermal LD_{50}	TGAI	A,B,H,I	Yes	00070075	No
81-3 - Inhalation LC_{50} - Rat	TGAI	A,B,H,I	No		Yes
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B,H	No		No 4/
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,H,I	Partially 5/	00070075	Yes
82-2 - 21-Day Dermal	TGAI	A,B,H,I	Partially 6/	00070075	Yes
82-3 - 90-Day Dermal	TGAI	A,B,H,I	No		Yes 14/
82-4 - 90-Day Inhalation - Rat	TGAI	A,B,H,I	No		Yes 7/
82-5 - 90-Day Neurotoxicity- Hen/Mammal	TGAI	A,B,H,I	No		No

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,B,H,I	Partially 8/	13/ 13/ 00070076, 00070077	Yes
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,B,H,I	Yes	GS01140001	No
83-3 - Teratogenicity - 2 species	TGAI	A,B,H,I	No 9/		Yes
83-4 - Reproduction, 2-generation	TGAI	A,B,H,I	No 10/		Yes
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,B,H,I	Partially 11/		Yes
84-2 - Chromosomal Aberration	TGAI	A,B,H,I	Partially 11/		Yes
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B,H,I	Partially 11/		Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,B,H,I	No		Yes 12/
85-2 - Domestic Animal Safety	Choice		No		No

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

§158.135 Toxicology
(continued)

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than 48 months.
4/ Anilazine is not structurally related to a known neurotoxin. Therefore, an acute neurotoxicity study is not required.
5/ The available subchronic feeding study in rats was classified as supplementary (see reviews for reasons). Therefore two additional subchronic feeding studies (rat and dog) are needed.
6/ The available 21-day dermal study in rabbits was classified as supplementary (see reviews for details). An additional study is required because anilazine has been shown to cause dermal irritation and necropsy indicated degenerative changes in brain, liver, heart and kidneys.
7/ A subchronic inhalation study may be required pending the outcome of the acute inhalation study.
8/ A 2-year feeding study in rats and a 1 year or longer feeding study in dogs are required.
9/ Two teratology studies are required, preferably one in the rat and one in the rabbit.
10/ A 2-generation reproduction study is required in the rat.
11/ For each test substance a battery of tests is required to assess potential to affect the qualitative or quantitative integrity of human genetic material. The objectives underlying the selection of a battery of tests for mutagenicity assessment are:
   a. To detect, with sensitive assay methods, the capacity of a test substance to alter genetic material in cells,
   b. To determine the relevance of these changes to mammals and, when mutagenic potential is demonstrated,
   c. To incorporate these findings in the risk assessment for heritable effects, oncogenicity, and possible, other health endpoints.

   The battery must include tests appropriate to address the following three categories of genetic effects:
   a. gene mutations
   b. structural chromosomal aberrations
   c. other mechanisms of mutagenicity (e.g., spindle inhibition, direct DNA damage) as appropriate for the tested chemical

   Specific battery test selection and protocol design should be submitted to the Agency for comment and evaluation. Registrants are encouraged to discuss results of preliminary testing with the Agency.

12/ Anilazine is not currently registered for any uses which would result in exposure to domestic animals through direct application for pest control or by consumption of treated foods.
13/ Submitted by Mobay Chemical Corporation. May be compensable.
14/ Only required for products used as additives to vinyl plastics.

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A,B,H	No		Yes
132-1 - Soil Dissipation	TEP		Not Applicable		
133-3 - Dermal Exposure	TEP	A,B,H	No		Yes
133-4 - Inhalation Exposure	TEP		Not Applicable		

1/ Composition: TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than _____.

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A,B,	Partial 5/	GS01140002	Yes
71-2 - Avian Dietary LC_{50}					
a) Upland Game Bird	TGAI	A,B,	Partial 5/	00030114 9/	Yes
b) Waterfowl	TGAI	A,B,	No		Yes
71-3 - Wild Mammal Toxicity	TGAI	A,B,	No		No 6/
71-4 - Avian Reproduction	TGAI	A,B,	No		Reserved 8/
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B,	No		Reserved 8/
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}					
a) Warmwater	TGAI	A,B,I	Yes	00095691 5/ 4/ GS01140003 5/ GS01140028 5/ 05009810 5/ 00095694	No
b) Coldwater	TGAI	A,B,I	Yes	00095695 5/ 4/ GS01140003	No
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A,B,I	Partial	GS01140003 5/	Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms (continued)					
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A	No		No 6/
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle					
a) Invertebrate	TGAI	A	No		Yes
b) Fish	TGAI	A	No		Yes
72-5 Fish - Life-Cycle	TGAI	A	No		Reserved 7/
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	A	No		Reserved 7/
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A	No		Reserved 7/

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

§158.145 Wildlife and Aquatic Organisms
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than 48 months.
4/ Study on its own fulfills guideline requirements.
5/ Subacute dietary on an upland game bird and waterfowl required. Study submitted must be combined with other studies to fulfill guideline requirements.
6/ Not applicable at this time.
7/ Reserved pending receipt and review of fish early-life stage and aquatic invertebrate life cycle tests.
8/ Reserved pending receipt and review of environmental fate data.
9/ Submitted by PBI Gordon, Inc. May be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirements	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP		No	-	No 4/
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI		No	-	No 4/
122-1 - Vegetative Vigor	TGAI		No	-	No 4/
122-2 - Aquatic Plant Growth	TGAI		No	-	No 4/
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI		No	-	No 4/
123-1 - Vegetative Vigor	TGAI		No	-	No 4/
123-2 - Aquatic Plant Growth	TGAI		No	-	No 4/
TIER III					
124-1 - Terrestrial Field	TEP		No	-	No 4/
124-2 - Aquatic Field	TEP		No	-	No 4/

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than _____.
4/ These requirements are generally waived unless it is believed there is a phytotoxicity problem.

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A,B,H	Yes	00036935	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,H	No		No 4/
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	A,B,H	No		No 5/
141-4 - Honey bee subacute feeding study	(Reserved) 6/				
141-5 - Field testing for pollinators	TEP	A,B,H	No		No 4/

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved) 7/				
142-2 - Aquatic insect life-cycle study	(Reserved) 7/				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved) 7/				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved) 7/				

TABLE A
GENERIC DATA REQUIREMENTS FOR ANILAZINE

§158.155 Nontarget Insect
(continued)

1/ Composition: TGAI = Technical grade of the active ingedrient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoo; I = Indoor.
3/ Data must be submitted no later than _____.
4/ As first tier (acute contact) test indicated low toxicity to honey bees, further testing is not required.
5/ Required only when product is intended for foliar application to seed alfalfa.
6/ Requirement reserved pending development of test methodology.
7/ Reserved pending decision as to whether data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ANILAZINE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	MP	Yes	GS01140026,GS01140027	No
61-2 - Statement of Composition	MP	No		Yes
61-3 - Discussion of Formation of Ingredients	MP	No		Yes
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	No		Yes 3/
62-2 - Certification of Limits	MP	Partially	GS01140021	Yes 4/
62-3 - Analytical Methods for Enforcement of Limits	MP	Partially	GS01140022	Yes
Physical and Chemical Characteristics				
63-2 - Color	MP	Yes	GS01140024 6/,GS01140025 6/	Yes 5/
63-3 - Physical State	MP	Yes	GS01140021,GS01140023 GS01140026,GS01140027	No
63-4 - Odor	MP	No		Yes
63-7 - Density, bulk density, or specific gravity	MP	Yes	GS01140024 6/,GS01140025 6/	Yes 5/

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ANILAZINE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry (continued)				
63-12 - pH	MP	No		Yes
63-14 - Oxidizing or reducing action	MP	No		Yes
63-15 - Flammability	MP	No		Yes
63-16 - Explodability	MP	No		Yes
63-17 - Storage Stability	MP	No		Yes
63-18 - Viscosity	MP	Not Applicable		
63-19 - Miscibility	MP	Not Applicable		
Other Requirements				
64- 1 - Submittal of Samples	Choice	Not Applicable		

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ANILAZINE

§158.120 Product Chemistry
(continued)

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than 6 months from the data of this Standard.
3/ This information was only submitted on the 92 % technical formulation.
4/ Quantitative methods are required to determine impurities present a >0.1 % by weight.
5/ This information was only submitted on the 95 % technical formulation.
6/ Submitted by Mobay Chemical Corporation. May be compensable.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ANILAZINE

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes	00070075 [3]	No
81-2 - Dermal LD_{50}	MP	Yes	00070075 [3]	No
81-3 - Inhalation LC_5^0 - Rat	MP	No		Yes
81-4 - Primary Eye Irritation - Rabbit	MP	No		Yes
81-5 - Primary Dermal Irritation	MP	No		Yes
81-6 - Dermal Sensitization	MP	No		Yes

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING ANILAZINE

§158.135 Toxicology
(continued)

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than 6 months.
3/ Submitted by Mobay Chemical Corporation. May be compensable.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This chapter applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10], as indicated by the following paragraphs of this chapter of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." [40 CFR §162.10(l)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Henry M. Jacoby
Phone No. (703) 557-1900
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has

shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Standard

00025729 Obrist, J.J.; Thornton, J.S. (1979) Soil Thin-Layer Mobility of Baycor(TM), Baytan(R), Drydene(R) and Peropal(TM). (Unpublished study received Dec. 21, 1979 under 3125-EX-168; prepared in cooperation with Agricultural Consultants, Inc.; submitted by Mobay Chemical Corp., Kansas City, MO.; CDL: 099185-M.)

00030114 DeWitt, J.B.; Stickel, W.H.; Springer, P.F. (1962) Wildlife Studies, Patuxent Wildlife Research Center, 1961-62. (Unpublished study received Jan. 2, 1980 under 2217-641; prepared by U.S. Fish and Wildlife Service, Patuxent Wildlife Service, Patuxent Wildlife Research Center, submitted by PBI-Gordon Corp., Kansas City, KS; CDL: 241577-B.)

00036935 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By Univ. of California, Dept. of Entomology. ?: UC, Cooperative Extension. (Leaflet 2287; published study.)

00070075 Treon, J.F.; Cleveland, F.P.; Hartman, L.; et al. (1953) The Immediate and Cumulative Toxicity of 2,4-Dichloro-6-(O-chloroanilino)-s-triazine (B0622). (Unpublished study received Feb, 5, 1956 under PP0063; prepared by Univ. of Cincinnati, Dept. of Preventive Medicine and Industrial Health, Kettering Laboratory, submitted by Mobay Chemical Corp., Kansas City, MO; CDL: 090061-A.)

00070076 Treon, J.F.; Cleveland, F.P.; Shaffer, M.S.; et al.(1955) The Toxicity of 2,4-Dichloro-6-(O-chloroanilino)-s-triazine When Administered Orally to Dogs in Serial Doses Over Prolonged Periods of Time. (Unpublished study received Feb. 5, 1956 under PP0063; prepared by Univ. of Cincinnati, Dept. of Preventive Medicine and Industrial Health, Kettering Laboratory, submitted by Mobay Chemical Corp., Kansas City, MO; CDL: 090061-B.)

00070077 Treon, J.F.; Cleveland, F.P.; et al. (1955) The Physiological Effects of Feeding Rats for Two Years on Diet Containing 2,4-Dichloro-6-(O-chloroanilino)-s-triazine (B-622). (Unpublished study received Feb.5, 1956 under PP0063; prepared by Univ. of Cincinnati, Dept. of Preventive Medicine and Industrial Health, Kettering Laboratory, submitted by Mobay Chemical Corp., Kansas City, MO; CDL: 090091-O.)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Standard

00095691 McCann, J.A. (1969) Dyrene 98.3%: Bluegill: Test No. 137. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL: 108543-A.)

00095694 McCann, J.A. (1969) Asgrow Turf Fungicide: Bluegill (Lepomis macrochirus): Test No. 212; Mobay 043135. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:130363-A)

00095695 McCann, J.A. (1968) Dyrene: Rainbow Trout (Salmo gardineri): Test No. 101 & 103:L Mobay 043136. (U.S. Agricultural Research Service, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:130364-A)

05009810 McCann, J.A.; Jasper, R.L. (1972) Vertebral damage to bluegills exposed to acutely toxic levels of pesticides. Transactions of the American Fisheries Society 101(2):317-322.

GS01140001 National Cancer Institute: Bioassay of Anilazine for Possible Carcinogenicity. CAS No. 101-05-3; NCI Carginogenesis Technical Report Series No. 104(1972).

GS01140002 Tucker, R.K. and Crabtree. D.G. (1970) Handbook of Toxicity of Pesticides to Wildlife. Bureau of Sport Fisheries and Wildlife, Denver Wildlife Research Center.

GS01140003 Johnson, W.W.; Finley, M.T. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. USDI Fish and Wildlife Service, Resource Publication 137.

GS01140004 Meagher, W.R.; Anderson, C.A.; Gonter, C.E.; Smith, S.B.; MacDougall, O. (1959) Colorimetric method for the determination of dyrene residues in plant material. Agric. Food Chem. 7: 558-560. Submitted by Chemagro Corp. as Report No. 4087 under PP0247; RCB Accession No. 113679.

GS01140005 Fassinger, W.P. (1956) B-622 Residues on Potatoes. Submitted by Chemagro Corp. under PP0063; RCB Accession No. 113156.

GS01140006 Holstein, S.; Fassinger, W.P. (1957) Dyrene Residues in Potatoes. Submitted by Chemagro Corp. as Report Nos. 1656, 1660, 1664, 1665, 1668 and 1736 under PP0131. RCB Accession No. 113346.

GS01140007 Holstein, S.; Adelman, D.; Anderson, C.; (1960) Dyrene Residues in Green and Dry Onions. Submitted by Chemagro Corp. as Report Nos. 1669, 2189, 2225, 2684 and 2837 under PP0215. RCB Accession No. 113584.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Standard

GS01140008 Anderson, C.A. (1959) Dyrene Residues in Green Onions. Submitted by Chemagro Corp. as Report No. 3534 under PP0215. RCB Accession No. 113584.

GS01140009 Anderson, C.A. (1960) Dyrene Residues in Shallots. Submitted by Chemagro Corp. as Report No. 4750 under PP0247. RCB Accession No. 113675.

GS01140010 Holstein, S.; Anderson, C.A. (1957) Dyrene Residues in Celery. Submitted by Chemagro Corp. as Report Nos. 1657, 1672, 1739 and 1740 under PP0131. RCB Accession No. 113346.

GS01140011 Adelman, D.P. (1958) Dyrene Residues in Celery. Submitted by Chemagro Corp. as Report Nos. 2154, 2155 and 2156 under PP0196. RCB Accession No. 113524.

GS01140012 Anderson, C.A. (1961) Dyrene Residues in Cucumbers. Submitted by Chemagro Corp. as Report Nos. 4888, 6722, 6724, 6733, 6737, 6744, 6750 and 6760 under PP0322. RCB Accession No. 113696.

GS01130013 Anderson, C.A. (1961) Dyrene Residues in Honeydew Melons, Watermelons, Canteloupe and Muskmelon. Submitted by Chemagro Corp. as Report Nos. 6720, 6721, 6726, 6727, 6728, 6730, 6731, 6735, 6745, 6746, 6747, 6748, 6754 and 6755 under PP0322. RCB Accession No. 113969.

GS01140014 Quattrochi, L.P.; Anderson, C.A. (1961) Dyrene Residues in Pumpkins. Submitted by Chemagro Corp. as Report No. 6743 under PP0322. RCB Accession No. 113969.

GS01140015 Anderson, C.A.; Blake, G.H.; Quattrochi, L.P. (1961) Dyrene Residues in Squash. Submitted by Chemagro Corp. as Report Nos. 6725, 6732, 6749, 6751, 6752 and 6753 under PP0322. RCB Accession No. 113969.

GS01140016 Anderson, C.A.; Johnson, F. (1961) Dyrene Residues in Blackberries. Submitted by Chemagro Corp. as Report Nos. 6761 and 6762 under PP0322. RCB Accession No. 113969.

GS01140017 Anderson, C.A.; Johnson, F.; Haines, R.G. (1962) Dyrene Residues in Raspberries. Submitted by Chemagro Corp. as Report Nos. 4313, 4760, 6734, 6736 and 6759 under PP0322. RCB Accession No. 113969.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Standard

GS01140018 Johnson, F.; Howitt, A.J.; Marucci, P.E.; Vaughn, E.K.; Reed, J.K.; Varney, E.H.; Cough, K. (1962) Dyrene Residues in Blueberries. Submitted by Chemagro Corp. as Report Nos. 8427, 8428, 8429, 8538, 8539, 8670 and 8686 under PP0363. RCB Accession No. 114143.

GS01140019 Boone, J.M.; Cough, K. (1962) Dyrene Residues in Cranberries. Submitted by Chemagro Corp. as Report Nos. 8368, 8369, 8370, 8371 and 8687 under PP0363. RCB Accession No. 114143.

GS01140020 Anderson, C.A. (1960) Dyrene Residues in Strawberries. Submitted by Chemagro Corp. as Report Nos. 3977, 4315, 4318, 4319, 4402, 4637, 4690 and 4749 under PP0247. RCB Accession No. 113675.

GS01140021 Chemagro Corp.(1967) Confidential Statement of Formula for EPA Registration No. 3125-199, dated Sept. 22, 1967. Submitted by Chemagro Corp.

GS01140022 EPA. (1975) Anilazine EPA-1 (tentative) and EPA-2 (tentative) in Manual of Chemical Methods for Pesticides and Devices. EPA, OTS.

GS01140023 Chemagro Corp. (1967) Confidential Statement of Formula for EPA Registration No. 3125-198 dated Sept. 22, 1967. Submitted by Chemagro Corp.

GS01140024 Chemagro Corp. (1960) Physicochemical properties submitted with Publication Bulletin dated February 26, 1960 under PP0247. RCB Accession No. 113675.

GS01140025 Chemagro Corp. (1959) Physicochemical properties submitted with Publication Bulletin dated April 8, 1959 under PP0215. RCB Accession No. 113584.

GS01140026 Aceto Chemical Co., Inc. (1975) Confidential Statement of Formula for EPA Registration No. 2749-94, dated May 17, 1975. Submitted by Aceto Chemical Co., Inc.

GS01140027 Chemagro Corp. (1966) Confidential Statement of Formula for Registration No. 3125-175, dated Jan. 26, 1966. Submitted by Chemagro Corp.

GS01140028 McCann, J.A. (1968) Dyrene: Bluegill Sunfish (Lepomis macrochirus) Test No. 110 U.S.Agricultural Research Service, Pesticides Regulation Div. Animal Biology Laboratory.

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by: Citing MRID#	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				

63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: Initiation of Reregistration Process for Pesticide Products Containing Anilazine as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the

steps you must take to maintain registration for your product(s). Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.

2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.

3. Sets out time-frames for submission of required data.

4. Explains how to revise labeling for maufacturing use products. (As the Guidance Document explains, labeling is not required at this time.)

5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that <u>if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended</u>.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

Henry M. Jacoby, Product Manager 21
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Telephone: 703/557-1900

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: FIFRA Section 3(c)(2)(B) Notice for Pesticide Products Composed of Multiple Active Ingredients That Contain Anilazine As One of the Active Ingredients

Dear Registrant:

This is a notice to you that EPA is requiring registrants of pesticide products containing the subject active ingredient to arrange to submit data to EPA concerning that active ingredient. As this notice explains, within 90 days from your receipt of this letter you must inform EPA either (1) that you are exempt from this requirement, or (2) how you will comply with the requirement. If you do not respond, or if you otherwise fail to comply with this notice, EPA may suspend the registration of your products containing that active ingredient. Attachment A is a list of those products. The authority for this notice is Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. Section a(c)(2)(B).

I. Why You Are Receiving This Notice Now

EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for data requirements in 1982.[1] Many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as were being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [see FIFRA Section 3(g)].

1/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

A new review procedure has been developed. Under it, EPA has issued Guidance Documents, each of which discussed a particular pesticide active ingredient. Each Guidance Document summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency currently does not have, compliance with standards of toxicity, composition, labeling, and packaging; and compliance with data support requirements. Because of the Monsanto v. Administrator litigation enjoining the Agency from implementing Section 3(c)(1)(D), additional information on data support requirements will be forthcoming. Registrants whose products contain this active ingredient have already received or will receive a copy of this enclosed Guidance Document.

FIFRA requires that a data submission requirement under Section 3(c)(2)(B) must be imposed on the registrants of all products to which the data are pertinent. Some of the data we have required persons subject to the reregistration program to submit are "generic" data which pertain to the safety of the active ingredient of a product, and thus are relevant to all products containing that ingredient (or to all products which contain that ingredient and have certain use patterns or formulation characteristics).

Since these data also may be pertinent to the registrability of your product containing the subject chemical, we are required by Section 3(c)(2)(B) to send you this notice. You are required to comply with this notice, but you are not required at this time to take steps to reregister your product, e.g., relabel your product.

II. What You Must Do to Comply With This Notice

Within 90 days of your receipt of this Notice, you must furnish to EPA a completed copy of the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, Attachment B) with appropriate attachments for each of your products. Agency records indicate that you do not qualify for the FIFRA Section 3(c)(2)(D) data exemptions, since the source of subject active ingredient is (1) not registered with EPA or/and (2) is not purchased from a firm other than your own. Since you are not exempt, you must determine what data you are required to submit [see paragraph (A) below] and how you will comply with the requirement [see paragraphs (B) through (D) below].

A. What Generic Data Must Be Submitted

You may ascertain which generic data you must submit by consulting the generic data table (Table A in the Guidance Document). That table shows the generic data needed to evaluate the continued registrability of all products containing the subject chemical and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, in the Pesticide Registration Guidelines*/, or data collected under protocols approved and issued by the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the continued registration of certain uses appearing in your current labeling, you may submit an application to have your registration amended by deleting those uses.

After determining whether you are required to submit data, and if so, which data, choose the appropriate option for each of your affected products.

B. Options Available for Complying With Requirements to Submit Data

You must submit to EPA within 90 days of your receipt of this Notice a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, Attachment B) for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and
   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must state which of the parties to the agreement will

respond to this Notice in the manner specified by paragraph c.2. above. A list of registrants with products containing this active ingredient is included for your information (see Attachment C).

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data." (EPA Form 8580-6, Attachment D)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed.

5. Change the source of your active ingredient to one that is (1) registered with EPA and (2) purchased from a firm that does not have ownership in common

6. Request voluntary cancellation of the registration(s) of your product(s) for which the data are needed.

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement between all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

C. Timeframes for Development and Submission of Required Data

The periods listed in Table A of the Guidance Document are the periods which the Agency will allow for development and submission of the data (measured from the date of receipt of this Notice).

D. Procedures for Requesting Changes In Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports from the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you want, or think that you will need, more time to generate the required data than is allowed by EPA's schedule, you must submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager named below. The extension request should state the reasons why you conclude that an extension is appropriate. You must strive to meet the deadline for submitting the required data while EPA considers your request.

If, after reviewing this Notice, you do not understand what you must do, or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way.

Henry M. Jacoby
Product Manager 21
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Telephone: 703/557-1900

Sincerely yours,

Douglas D. Campt, Director
Registration Division (TS-767)